

## § 426.100

## 42 CFR Ch. IV (10–1–10 Edition)

- 426.515 CMS' role in making the NCD record available.
- 426.516 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the NCD review process.
- 426.517 CMS' statement regarding new evidence.
- 426.518 NCD record furnished to the aggrieved party.
- 426.519 NCD record furnished to the Board.
- 426.520 Withdrawing an NCD under review or issuing a revised or reconsidered NCD.
- 426.523 Withdrawing a complaint regarding an NCD under review.
- 426.525 NCD review.
- 426.531 Board's review of the NCD to apply the reasonableness standard.
- 426.532 Discovery.
- 426.535 Subpoenas.
- 426.540 Evidence.
- 426.544 Dismissals for cause.
- 426.545 Witness fees.
- 426.546 Record of hearing.
- 426.547 Issuance, notification, and posting of a Board's decision.
- 426.550 Mandatory provisions of the Board's decision.
- 426.555 Prohibited provisions of the Board's decision.
- 426.557 Optional provisions of the Board's decision.
- 426.560 Effect of the Board's decision.
- 426.562 Notice of the Board's decision.
- 426.563 Future new or revised or reconsidered NCDs.
- 426.565 Board's role in making an LCD or NCD review record available.
- 426.566 Board decision.
- 426.587 Record for appeal of a Board NCD decision.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh)

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### Subpart A—General Provisions

#### § 426.100 Basis and scope.

(a) *Basis.* This part implements sections 1869(f)(1) and (f)(2) of the Act, which provide for the review of LCDs, NCDs, and certain determinations that are deemed to be NCDs by statute.

(b) *Scope.* This subpart establishes the requirements and procedures for the review of LCDs and NCDs.

#### § 426.110 Definitions.

For the purposes of this part, the following definitions apply:

*Aggrieved party* means a Medicare beneficiary, or the estate of a Medicare beneficiary, who—

(1) Is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare+Choice plan, or in another Medicare managed care plan);

(2) Is in need of coverage for a service that is denied based on an applicable LCD (in the relevant jurisdiction) or an NCD, regardless of whether the service was received; and

(3) Has obtained documentation of the need by the beneficiary's treating physician.

*Board* means the Departmental Appeals Board.

*Clinical and scientific experts* mean experts that are consulted by the ALJ or Board as independent and impartial individuals, with significant experience and/or published work, pertaining to the subject of the review.

*Contractor* means a carrier (including a Durable Medical Equipment Regional Carrier), or a fiscal intermediary (including a Regional Home Health Intermediary) that has jurisdiction for the LCD at issue.

*Deemed NCD* means a determination that the Secretary makes, in response to a request for an NCD under section 1869(f)(4)(B) and (C) of the Act, that no national coverage or noncoverage determination is appropriate, or the Secretary's failure to meet the deadline under section 1869(f)(4)(A)(iv) of the Act.

*New evidence* means clinical or scientific evidence that was not previously considered by the contractor or CMS before the LCD or NCD was issued.

*Party* means an aggrieved party, which is an individual, or estate who has a right to participate in the LCD or NCD review process, and, as appropriate, a contractor or CMS.

*Proprietary data* and *Privileged information* means information from a source external to CMS or a contractor, or protected health information, that meets the following criteria:

(1) It is ordinarily protected from disclosure in accordance with 45 CFR part 164, under the Trade Secrets Act (18 U.S.C. 1905) or under Exemptions 4 or 5 of the Freedom of Information Act (5 U.S.C. 552) as specified in 45 CFR 5.65.